

MEDICAL DEVICE DAILY™

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AHEAD OF SCHEDULE

Medtronic expands TAVI access in Europe with introduction of XL-sized Evolut R valve

By John Brosky, Contributing Writer

PARIS – A month earlier than expected, Dublin-based [Medtronic plc](#) said it has received the CE mark for the [Corevalve Evolut R](#) 34 millimeter transcatheter aortic valve implantation (TAVI).

The clearance for commercialization in the European Union follows approval by the U.S. FDA in October 2016, and rounds out the top end of the Medtronic TAVI portfolio that includes 23 millimeter, 26 millimeter and 29 millimeter valves.

“We look forward to working with physicians across Europe to offer this highly anticipated valve size to the thousands of patients who were previously unable to

[See Medtronic, page 3](#)

WILL COMBAT DEADLY MODS

APD initiates launch of new hemodynamic monitoring technology for intensive care units

By Bernard Banga, Staff Writer

Paris – [Advanced Perfusion Diagnostics SAS](#) (APD) has started a limited launch of its [Ikorus](#) non-invasive technology for regional hemodynamic patient monitoring in several European countries. This new device aims to improve treatment quality

[See Ikorus, page 4](#)

FOSTERING DOMESTIC INNOVATION

New review system set to speed up approval of innovative drugs, devices

By Pearl Liu, Staff Writer

HONG KONG – Chinese drug and medical device officials have highlighted a new review system as a priority for the coming year, aiming to speed up the approvals of innovative devices and drugs. The move shows the country’s dedication to up the level of its health care industry and foster more domestic innovation.

[See China, page 5](#)

REGULATORY

FDA offers little in payer communications draft guidance, reopens the off-label docket

By Mark McCarty, Regulatory Editor

The FDA draft guidance for communications with payers and formulary committees was widely anticipated, but offers little in the way of surprises. The agency has drawn very tight lines about what may be discussed for approved products, disallowing even a communication about the long-term benefits of a drug approved only for acute treatment of the underlying disease.

The payer communication draft guidance followed the release of a draft guidance for communication regarding on-label use of drugs and devices, continuing what seems an effort to clarify some of the issues surrounding off-label promotions without directly addressing that issue. The on-label use draft guidance was mandated by

[See FDA, page 6](#)

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ORTHOPEDICS EXTRA

Executive Editor Holland Johnson
on one of med-tech’s key sectors

[Read this week’s Thursday Special](#)



APPOINTMENTS AND ADVANCEMENTS

Personal Genome Diagnostics Inc. (PGDx), a Baltimore-based provider of advanced cancer genome testing products and services, reported that James Lewis has joined the company as senior vice president of corporate development. Lewis brings broad biopharmaceutical industry experience to the development and execution of PGDx's growth strategy. He will oversee strategic planning, collaboration initiatives and fundraising activities, including launching a planned series B financing in 2017. Before joining PGDx, Lewis served as vice president of business development at Esperance Pharmaceuticals where he led strategic partnering and fundraising initiatives.

Profound Medical Corp., a Mississauga, Ontario-based company specializing in prostate care, reported the appointment of Kenneth Galbraith to its board. In connection with Galbraith's appointment, Steven Plymale has resigned from the company's board, but remains president and CEO. Galbraith has more than 25 years of experience acting as an executive, director, investor and advisor to companies in the biotechnology, medical device, pharmaceutical and health care sectors. Galbraith currently serves on the board of directors of Macrogenics and Prometic Life Sciences.

Seno Medical Instruments Inc., a San Antonio-based company focused on diagnosing breast cancer through the development of an opto-acoustic imaging device, reported the appointment of Steve Miller as senior vice president of engineering. Miller previously served as the vice president of product realization at Fujifilm Sonosite. Miller has dedicated the majority of his 30-year career to the development of medical imaging products. He is personally an inventor on more than 30 patents and led teams that received more than 200 patents.

Medical Device Daily presents Patent Highlights, an excerpt of the most important med-tech patents from this week's Cortellis Patents Gazette. See the attachment at the end of this edition.

FINANCINGS

Enteromedics Inc., the St. Paul, Minn.-based developer of medical devices using neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders, reported the pricing of an underwritten public offering of units for gross proceeds of \$16.5 million, prior to deducting underwriting discounts and commissions and offering expenses payable by Enteromedics. The offering is comprised of class A units, priced at a public offering price of \$5.31 per unit, with each unit consisting of one share of common stock and one five-year warrant to purchase one share of common stock with an exercise price of \$5.84 per share, and class B units, priced at a public offering price of \$1,000 per unit, with each unit comprised of one share of preferred stock, which is convertible into 188 shares of common stock, and warrants to purchase 188 shares of common stock. A total of 751,412 shares of common stock, 12,531 shares of preferred stock convertible into 2,359,887 shares of common stock, and warrants to purchase 3,111,299 shares of common stock will be issued in the offering. The securities comprising the units are immediately separable and will be issued separately. The closing of the offering is expected to take place on or about Jan. 23, subject to the satisfaction or waiver of customary closing conditions. Ladenburg Thalmann & Co. Inc., a subsidiary of Ladenburg Thalmann Financial Services Inc., is sole book-running manager in connection with the offering.

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CONTACT US

newsdesk@medicaldevicedaily.com

Donald R. Johnston, (770) 810 3118 // Holland Johnson, (770) 810-3122 // Omar Ford, (770) 810-3125 // Mark McCarty, (703) 966-3694 // Andrea Gonzalez, (770)-810-3049 // Penney Holland, (770) 810-3047 // Lynn Yoffee, (770) 810-3123

OUR NEWSROOM

Lynn Yoffee (News Director), Holland Johnson (Executive Editor), Mark McCarty (Regulatory Editor), Andrea Gonzalez (Production Editor), Omar Ford (Staff Writer); Europe // John Brosky (Staff Writer); Asia // Pearl Liu, Haky Moon, Alfred Romann & Cornelia Zou (Staff Writers); Latin America // Sergio Held (Staff Writer)

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BUSINESS OFFICE

Donald R. Johnston (Senior Director, Current Awareness), Penney Holland (Web Production Manager)

